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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,592

03/19/2004

William Galbraith

80154

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04/07/2005

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EXAMINER

YU, MELANIE J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/804,592	GALBRAITH, WILLIAM	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's amendment filed March 7, 2005 has been entered. Claims 7-23 and 32-49 are canceled. Claims 1-6 and 24-31 are pending.

#### ***Election/Restrictions***

2. Applicant's election without traverse of group I, claims 1-6 and 24-31, in the reply filed on March 7, 2005 is acknowledged.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 and 24-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 24, it is unclear whether the salt or ester thereof refers to a salt or ester of bromosulfophthalein or any salt or ester that can be a ligand.

With respect to claims 28 and 29, it is unclear whether the one or more additional supports are intended for one or more non-albumin proteins because it is vague as to whether more than one non-albumin protein can be bound to only one additional support.

Regarding claim 31, the Protein G cartridge, Protein A cartridge, and Protein A and G cartridge are vague because it is unclear what is encompassed by "cartridge". It is unclear whether a cartridge is the insoluble support of claim 29.

Claims 28-31 recite the phrase "adapted to be capable of binding", which is vague because it is unclear what structural limitations are necessary for the support to be adapted for

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binding. It is unclear what type of adaptation for binding is required, for instance if ligands are attached to the support or whether the support requires a type of coating which enhances binding.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundrehagen (US 5,919,708).

Sundrehagen teaches an apparatus comprising an insoluble support (a solid support of beads of cross-linked agarose are insoluble; col. 11, lines 46-49) having a ligand of bromosulfophthalein attached thereto (col. 11, lines 49-54), wherein the insoluble support is contained or supported in a container of columns (separation is obtained by filtering through a filter comprising a filter surface, wherein the filter surface is an insoluble support and the filter is a container, col. 11, lines 19-25). Sundrehagen further teaches the filter container being a filter plate (col. 11, lines 21-25) and the insoluble support being a matrix (col. 11, lines 47-48).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 24 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieper et al. (US 2002/0127739) in view of Sundrehagen (US 5,919,708).

Pieper et al. teach a column comprising one or more additional supports capable of binding one or more non-albumin proteins (par. 0067), wherein the supports include one or more supports capable of binding IgA and IgG (different matrices carrying different binding agents to remove proteins from a sample is provided at par. 0067; sample proteins of IgG and IgA are listed at pg. 9, Table 1). Pieper et al. fail to teach a ligand of bromosulfophthalein.

Sundrehagen teaches a ligand of bromosulfophthalein attached to an insoluble support (col. 11, lines 46-65) of a filter plate (col. 11, lines 21-25), in order to bind albumin to the support.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the column of Pieper et al., a binding agent of bromosulfophthalein as taught by Sundrehagen, in order to provide an anionic ligand specific to albumin, which strongly influences the affinity of albumin to the ligand, provides detectable properties upon binding to ensure removal and binds albumin separately from other proteins to ensure sufficient removal of albumin.

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Regarding claims 30 and 31, Pieper et al. teach a support adapted to be capable of binding IgA (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgA has a separate column body par. 0102) and a support adapted to be capable of binding IgG (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgG has a separate column body par. 0102) wherein the support comprises protein A and G cartridge (a column comprising protein G and A bind IgG; see under Table 1).

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Applicant is advised that should claims 2 and 4 be found allowable, claims 3 and 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

7. Claims 1-6 and 24-31 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 and 24-31 of copending Application No. 10/922,560. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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03/31/05